

### **REMARKS**

In the Office Action that issued on March 4, 2010, each of claims 1-59 were rejected. By way of this Amendment and Response to the Office Action, claims 1-30 and claims 53-57 have been cancelled, claims 34 and 45 have been amended, claims 31-52 and 58-59 remain as previously presented, and new claims 60-95 are added. The claims as previously pending included some sets of dependent claims that were not clustered together in numerical order. To present these sets of dependent claims with better organization, the claims have been presented again as new claims. All of the independent claims that were previously pending are presented in this Amendment and Response. Below is a table that provides a correlation between the independent claims as now pending and those that were previously pending.

Independent Claim Number	Previous Number of the Same Independent Claim
31	31
42	42
60	7
75	19
80	20
83	1
92	18

Below is a table that provides a correlation between all of the claims as now pending and those that were previously pending.

Claim Number	Previous Number
31-52	31-52
58-59	58-59
60-65	7-12
66	
67-70	13-16
71	17
72	23
73	24
74	54
75	19
76	27
77	28
78	56
79	
80	20
81-83	29-30
84-89	1-6
89-90	21-22
91	53
92	18
93-94	25-26
95	55

Claims 31-52 and 58-59 are method claims. Claims 60-82 are device claims. Claims 83-95 are device claims that recite certain elements in means-plus-function format.

As noted above, independent claims 31 and 42 remain unchanged. Independent claims 60, 75, 83, and 92 recite verbatim the language that was previously recited in claims 7, 19, 1 and 18. Claim 80 recites verbatim the language of previously pending claim 20 except that claim 80 specifies that “each ring is an integral structure comprising a plurality of flexible segments.” The same limitation is recited in amended claims 34 and 45, new claims 66 and 79. Applicants respectfully submit that the newly added claims are fully supported by the Application as originally filed and that the amendments to the claims add no new matter to the Application.

#### Rejection under 35 U.S.C. § 103

Claims 1-13, 15-16, 18-37, 39-48, and 50-59 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,523,592 to Daniel (hereafter “Daniel”) in view of U.S. Patent No. 6,503,259 to Huxel et al. (hereafter “Huxel”); and claims 14, 17, 38, and 49 stand rejected under 35 U.S.C. § 103 as being unpatentable over Daniel in view of Huxel, and further in view of U.S. Patent No. 5,868,763 to Spence et al. (hereafter “Spence”). The Applicants respectfully traverse these rejections.

It is well settled that the Patent Office bears the burden of establishing a *prima facie* case of obviousness. To meet this burden, the Patent Office must set forth an

explicit analysis supporting an obviousness rejection. M.P.E.P. § 2142 (8th ed., rev. 6). In particular, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *in re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). If the evidence presented in the analysis does not meet the preponderance of evidence standard (i.e., the evidence fails to show that it is more likely than not that an obviousness rejection is proper), then the rejection fails to set forth a *prima facie* case of obviousness. See *id.* Moreover, if “the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” M.P.E.P. § 2143.01 (VI).

The Applicant respectfully asserts that the rejections in the Office Action fail to set forth a *prima facie* case of obviousness for at least the reasons that (1) Daniel has been mischaracterized such that the asserted rationale for combining the teachings of Daniel and Huxel fails to meet the preponderance of evidence standard with respect to the propriety of their combination and (2) the proposed combination would change the principle of operation of each of Daniel and Huxel. Brief descriptions of each of the disclosures of Daniel and Huxel are set forth hereafter, followed by an analysis of each of the enumerated reasons that the obviousness rejection set forth in the Office Action fails to set forth a *prima facie* case of obviousness.

Daniel

Daniel discloses an anastomotic device that consists of two separate unitary pieces, each of which defines a coupler device 10. As shown in FIG. 5 (reproduced below), each vessel is penetrated by hooks 20' before the coupler devices 10 are interlocked together. FIG. 5 clearly shows that both vessel are penetrated so it was incorrect to characterize Daniel in the Office Action as showing vessels held "together without requiring penetration of the second vessel."

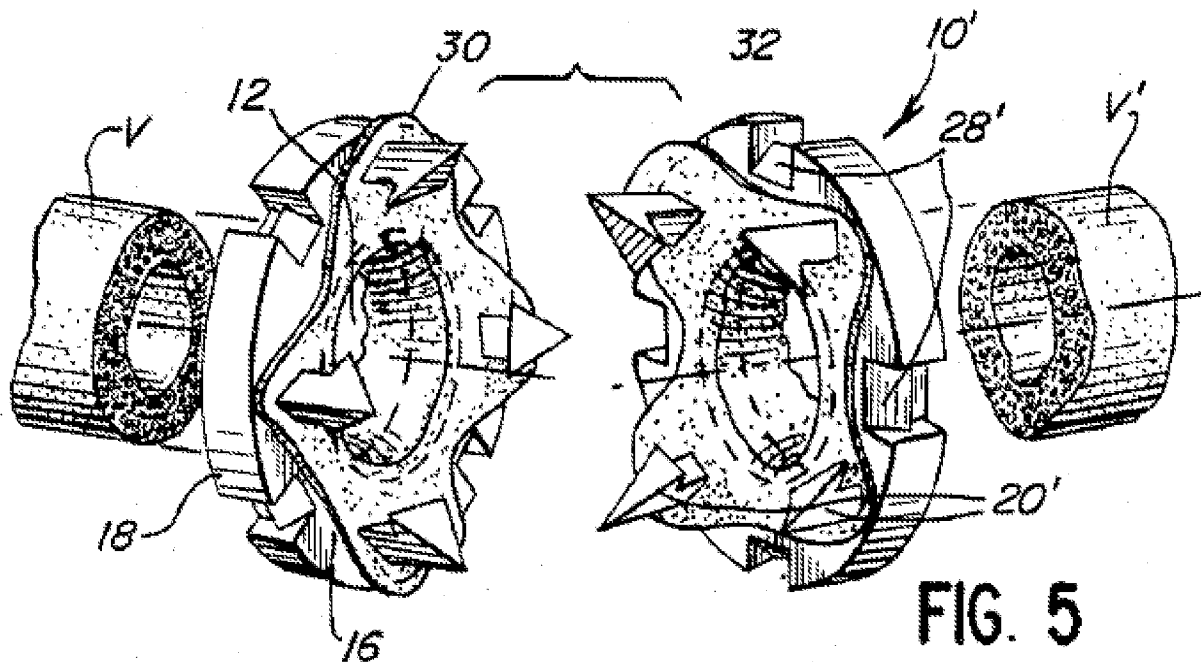


FIG. 5 of Daniel

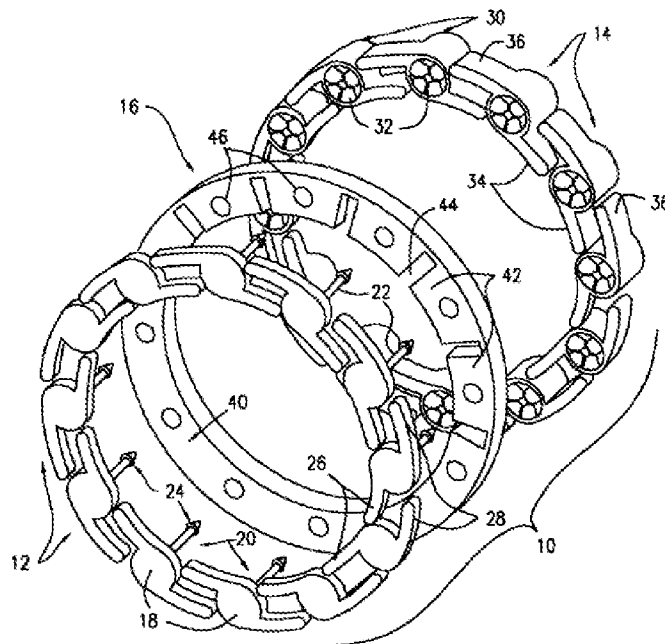
Moreover, the principle of operation in Daniel is expressly reliant on the interplay of the resiliency of the hooks 20 and the immobility of the wedges 28 over which they snap.

Huxel

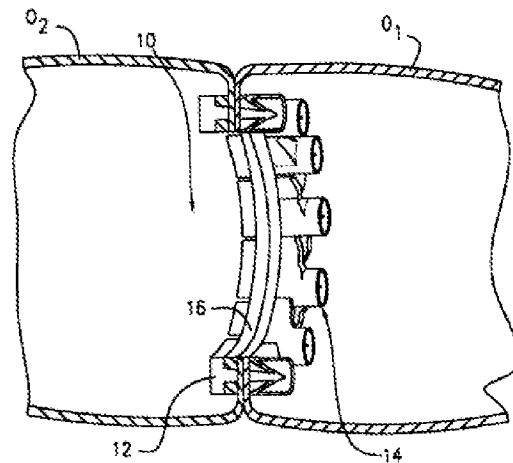
Huxel states that certain problems with prior art anastomotic devices have “been addressed by biodegradable anastomotic fastening systems which break down in the presence of bodily fluids at a predetermined rate. . . [and such] known ring-type fastener systems provide a rigid anastomosis, limiting the radial expansion of the anastomosis and interrupting peristalsis.” Column 1, lines 42-45 and 64-67. Recall that this is the exact manner in which the devices of Daniel function. This feature is characterized by Huxel as a “limitation” of the prior art, and further states that these limitations “are addressed by the present invention.” Column 5, lines 1-5. Thus, Huxel clearly teaches away from the use of anastomotic devices such as those disclosed in Daniel.

As shown, for example, in FIGS. 1 and 8 (reproduced below) and as described in columns 3 and 4, the device of Huxel comprises a plurality of components that are positioned in a circular arrangement and remain discrete before and after they are attached together. Each of the fasteners 11 comprises a tissue piercing element 12 and a receiver element 14. Each of the fasteners 11 is structurally independent, and the plurality of fasteners “approximate concentric segmented rings.” Column 3, lines 36-47 and 59-60. Each interlocked pair 12, 14 is structurally independent from any other pair of interlocked pair of interlocked elements 12, 14, allowing the interlocked pairs of

elements 12, 14 to move independently of the others, being constrained and held in relative proximity by their affixation to a common substrate, e.g., peripheral flanges of tissue on the conjoined severed ends of the intestine. This relative structural independence gives rise to what can be described as “flexibility” of the fastener array 10. Column 3, line 66 and column 4, lines 1-7. Clearly, it is essential to the operation of the device of Huxel that the tissue piercing element 12 pierce through the ends of both tubes that are being anastomosed.



**FIG. 1 of Huxel**



**FIG. 8 of Huxel**

1. The rationale for combining Daniel and Huxel fails to meet the preponderance of evidence standard with respect to the propriety of their combination

In the Office Action, it is asserted that “[i]t would have been obvious to one of ordinary skill in the art at the time of invention to modify the rings of Daniel to be expandable and contractible, as taught by Huxel et al., in order to maintain the connection between the rings and the tissue, as well as permit peristalsis.” Page 3. The Applicants respectfully submit that this assertion of obviousness fails to meet the preponderance of evidence standard, as it is not at all clear how the devices of Daniel could be modified by the teachings of Huxel. Disparate features from Daniel and Huxel are merely cobbled together without regard to the teachings of these references and by incorrectly characterizing Daniel. The Applicants thus respectfully submit that this proposed combination is improper and constitutes an impermissible hindsight



reconstruction. Moreover, neither Daniel nor Huxel, whether alone or in combination, teaches all of the elements of the independent claims.

As previously discussed, Huxel acknowledges the existence of devices such as those taught in Daniel, explicitly discredits such devices and their methods of operation, and then sets forth a vastly different apparatus and method for creating an anastomosis. It is not clear from the Office Action how or why one skilled in the art would be prompted to combine the teachings of Daniel and Huxel, let alone how such a combination could result in the invention claimed in the Present Application.

The Applicants respectfully note that “[w]here the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another.” M.P.E.P. § 2143.01. Here, the teachings of the references not only conflict, but Huxel explicitly teaches away from Daniel. Yet the Office Action is devoid of any discussion of why one skilled in the art would be prompted to combine these teachings, or how one skilled in the art could even do so. Accordingly, the Applicants respectfully assert that the Office Action fails to set forth a *prima facie* case of obviousness with respect to Daniel and Huxel.

2. The proposed combination would change the principle of operation of Daniel and Huxel

As previously discussed, the devices of Daniel are designed to maintain a fixed diameter and to anastomose two tubular structures while penetrating the tubular

structures. In contrast, the devices of Huxel do not define a diameter, or at least not in the same manner as the devices of Daniel. It might be said that a series of the discrete components of Huxel arranged at the ends of two tubular structures define a diameter, and this diameter can change with a change in the diameter of the tubular structures. However, this diameter would constitute a diameter between separate discrete components, and would not be a diameter defined by any of the discrete components individually. In any event, both the devices of Daniel and those of Huxel operate only by penetrating the tubular structures that are being attached to each other.

In sum, any alteration of the teachings of Daniel to cause its devices to have a variable diameter would change the principle of operation of these devices. Accordingly, the Applicants respectfully assert that the Office Action fails to set forth a *prima facie* case of obviousness with respect to Daniel and Huxel.

#### Claims 14, 17, 38, and 49

The Applicants respectfully submit that Spence fails to remedy any of the shortcomings of Daniel and Huxel discussed above. Accordingly, it is submitted that claims 14, 17, 38, and 49 are patentable for at least the reasons discussed above.

#### Summary

In view of the foregoing, the Applicants respectfully submit that the rejection of the claims based on a combination of Daniel and Huxel is improper, as Daniel is mischaracterized and the Office Action fails to recite a proper *prima facie* case of

obviousness with respect to these references. The Applicants thus respectfully request that the rejection of the claims under 35 U.S.C. § 103 be withdrawn.

### **CONCLUSION**

In view of the foregoing, it is believed that all of the claims are patentable in their present form and thus a Notice of Allowance is respectfully requested. The Examiner is invited to contact the undersigned attorney should any impediment to the prompt allowance of this Application remain that is susceptible to being clarified by a telephonic interview or overcome by an examiner's amendment.

DATED this 7th day of September, 2010.

Respectfully submitted,

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